**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

KATHLEEN BIESTERFELD, Individually and as Respresentative of N.B.; and RONALD BIESTERFELD,

Plaintiffs,

v.

ARIOSA DIAGNOSTICS, INC.

Defendant.

Case No. 1:21-cv-03085
**Judge Georgia N. Alexakis**

## SECOND AMENDED COMPLAINT AT LAW

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Representative of N.B., and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and in complaining of the Defendant ARIOSA DIAGNOSTICS, INC. allege as follows:

### I. INTRODUCTION

1. This action is brought pursuant to the laws of the State of Illinois to redress personal injury and economic loss sustained by what is termed under Illinois law as "wrongful birth" for extraordinary expenses and emotional distress. This Second Amended Complaint adds a failure to warn count pursuant to Judge Edmund E. Chang's Memorandum and Order of March 25, 2024. Plaintiffs here have amended the negligence claim (Count III.) Per Magistrate Judge Maria Valdez's minute entry of September 26, 2024, the Rule 16(b) deadline to add parties or to amend pleadings is February 3, 2025. (ECF Dkt. No. 93.)

## II. JURISDICTION

2. Jurisdiction is based on Title 20 U.S.C. §1332. The parties are citizens of different states and the amount in controversy is in excess of $75,000.
3. At all times Plaintiffs KATHLEEN BIESTERFELD and RONALD BIESTERFELD resided in the City of Roselle, County of DuPage, State of Illinois.
4. Defendant ARIOSA DIAGNOSTICS, INC. is a corporation headquartered in the City of San Jose, County of Santa Clara, State of California.
5. ARIOSA DIAGNOSTICS CLINICAL LABORATORY is a division of ARIOSA DIAGNOSTICS, INC. (collectively "ARIOSA") and is also located in the City of San Jose, County of Santa Clara, State of California.
6. Defendants engage in continuous trade and commerce in Illinois including all counties, by marketing and selling prenatal test kits claimed to detect Down Syndrome and other genetic abnormalities to customers and ultimate consumers such as the BIESTERFELDS through physicians in Illinois.
7. The BIESTERFELDS purchased a product of ARIOSA in Illinois.

## III. FACTS COMMON TO ALL COUNTS

8. Plaintiffs KATHLEEN BIESTERFELD and RONALD BIESTERFELD became pregnant with their first child in 2017. They sought prenatal care through DuPage Medical Group's OBY-GYN clinic ("DMG") and saw Dr. Mitchell, Dr. Wirth and Dr. Patsavas of DMG.
9. As KATHLEEN BIESTERFELD was 35 at the time, the BIESTERFELDS requested genetic testing be performed by their doctors to determine the presence of Down Syndrome (Trisomy 21 defect) or another genetic abnormality. They were prepared to abort the pregnancy should they learn there was present Down Syndrome.
10. The doctors at DMG offered and recommended a genetic test from ARIOSA called the Harmony Prenatal Test ("ARIOSA Test").
11. The doctors at DMG orally represented to the BIESTERFELDS they were told by ARIOSA that the test was 100% accurate. In addition, the doctors at DMG provided to the BIESTERFELDS an ARIOSA brochure for marketing from ARIOSA.
12. The BIESTERFELDS then went home and researched the accuracy of the ARIOSA test, and found on ARIOSA's website a page that represented, advertised, boasted, and guaranteed the ARIOSA Test had a 100% accuracy rate in detecting Trisomy 21.
13. The BIESTERFELDS concluded based on review of all the information provided by ARIOSA that the ARIOSA Test had a 100% accuracy rate and relied on the representations of ARIOSA through the doctors at DMG, the ARIOSA brochure, and the ARIOSA website.

14. ARIOSA's advertising was deceptive on its face as ARIOSA knew the combination of the training it provided to doctors, along with its brochures and on-line advertising, would provide a net impression to consumers and the general populace the ARIOSA Test was 100% accurate.
15. The BIESTERFELDS, as a pregnant couple near or over 35 and concerned about genetic defects more prevalent to older mothers, were the very consumers ARIOSA targeted by its advertising and marketing.
16. The BIESTERFELDS then requested that the doctors at DMG order and administer the ARIOSA Test.
17. The ARIOSA Test is performed by a blood draw from the arm. It costs over $400. After the BIESTERFELDS asked DMG to perform the ARIOSA Test, the Test was ordered by Dr. Patsavas and blood was collected on July 18, 2017 at the DMG clinic in Downers Grove, Illinois. The blood was then sent to the ARIOSA labs in San Jose, California.
18. DMG charged the BIESTERFELDS for the ARIOSA Test. As the BIESTERFELDS had the forethought to obtain medical insurance, DMG agreed to accept payment direct through the BIESTERFELD'S insurer instead of requesting the BIESTERFELDS pay for the ARISOA Test first and later request reimbursement from their insurer.
19. The BIESTERFELDS became consumers of the ARIOSA Test when they requested that the doctors at DMG order and administer the ARIOSA Test, and later paid for it.
20. DMG received the results of the ARIOSA Test July 23, 2017. The DMG clinic reported to MRS. BIESTERFELD via telephone the ARIOSA Test was negative.

21. The BIESTERFELDS were led to believe by ARIOSA, and did believe, that the ARIOSA Test was 100% conclusive that their baby did not have Down Syndrome, or Trisomy 21 defect.

22. N.B. was born on February 6, 2018, and was diagnosed with Down Syndrome, or Trisomy 21 defect. This is the very defect the BIESTERFELDS had taken the ARIOSA Test to discover.

23. N.B. now requires 24-hour care, which must be delivered by his parents the BIESTERFELDS.

24. Following the birth, the BIESTERFELDS conducted an investigation as to why the ARIOSA Test was wrong and created a false negative when their baby had Trisomy 21 in every cell of his body.

25. The BIESTERFELDS went on-line again in May 2018 to look at the ARIOSA website and take a screenshot. They discovered the website they viewed in July 2017 was still up unchanged such that it still falsely advertised the ARIOSA Test was 100% accurate. They took a screenshot of the same false advertisement they had viewed which lead them to buy the ARIOSA Test. (Attached hereto as Exhibit "A" is the online advertising screen shot from ARIOSA's website from May 2018).

26. ARIOSA trained its doctors that the ARIOSA Test tests only fetal DNA. A test for only fetal DNA would be 100% accurate.

27. In fact, the ARIOSA Test tests placental DNA. Placental DNA is a mixture from the mother and baby, such that the mixing creates mosaicism, where some cells from the mother are analyzed, which are normal and free of trisomy 21 defect, causing a negative test result as occurred here.

28. ARIOSA did not disclose to treating physicians, including to those at DMG, that placental DNA was being tested, and not fetal DNA.

29. ARIOSA knew of its misrepresentation and knew this representation would lead doctors to market the ARIOSA Test for ARIOSA and claim 100% accuracy to patients such as the BIESTERFELDS. This caused physicians to pass on this false information to the ultimate consumers and patients such as the BIESTERFELDS, causing them to believe the Test is 100% accurate.

30. The BIESTERFELDS discovered they had the option to conduct other testing had they not used the ARIOSA Test. This available testing involved either a blood test to test the levels of pregnancy-associated plasma protein-A (PAPP-A), or an ultrasound to detect fluid at the back of the fetus' neck, or chorionic villus sampling (CVS), or amniocentesis. These tests could have been obtained within the time period allowed in Illinois for an abortion and when done together provided greater accuracy than the ARIOSA Test.

31. If not for the conduct of ARIOSA to provide false information passed through the doctors, from the ARIOSA brochure and from the ARIOSA website, the BIESTERFELDS would have conducted other testing that would have discovered the fetus had trisomy 21 and terminated the pregnancy.

32. The birth of N.B. caused the BIESTERFELDS to have extraordinary expenses, which will occur at least until N.B.'s 18$^{th}$ birthday, and now are projected to be in excess of $4,000,000. The birth of N.B. with the continued care caused and will cause emotional distress to the BIESTERFELDS.

**COUNT I—VIOLATION OF CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT**

33. Plaintiffs bring this cause of action pursuant to 815 ILCS 505/2, the Consumer Fraud and Deceptive Business Practices Act, in their individual capacities.

34. Section 1(e) defines a consumer:

> (e) The term "consumer" means any person who purchases or contracts for the purchase of merchandise not for resale in the ordinary course of his trade or business but for his use or that of a member of his household.

35. ARIOSA sold the ARIOSA Test to Illinois consumers and patients of obstetrician-gynecologists through the physicians such as those at DMG .

36. The BIESTERFELDS were consumers of the ARIOSA Test as they purchased the Test through DMG from ARIOSA.

37. Section 2 of the Consumer Fraud and Deceptive Business Practices Act provides:

> Sec. 2. Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act.

38. ARIOSA made its false statements that were communicated to the BIESTERFELDS in the training provided to physicians such as those at DMG who treated MRS. BIESTERFELD, in the marketing in its brochure, and in its marketing on its website.

39. Defendants used unfair or deceptive acts or practices in one or more of the following ways:

    a. Fraudulently induced and misrepresented that the ARIOSA Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;

    b. Misrepresenting that the ARIOSA Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;

    c. Misrepresenting the limitations of and alternatives to the ARIOSA Test;

    d. Misrepresenting that the ARIOSA Test is more accurate than traditional first trimester screening tests;

    e. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested;

    f. Misrepresenting the probability and rate at which the ARIOSA Test could produce false negative results; and

    g. Using deceptive advertising to create the image, impression and belief by consumers and physicians that the use of the ARIOSA Test was safe, reliable, and effective for detecting fetal chromosomal abnormalities, and having no reasonable grounds to believe such representations to be true.

40. ARIOSA made the foregoing misrepresentations with the intent that Plaintiffs, and others similarly situated to Plaintiffs, would rely on such misrepresentations.

41. ARIOSA knew or had reason to know that the foregoing misrepresentations were false, unfair or deceptive to Plaintiffs and others similarly situated to Plaintiffs.

42. Defendants made the foregoing misrepresentations or engaged in the foregoing deceptive acts and/or practices in the course of commerce.

43. Due to Defendants' misrepresentations and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and concealing material information, Defendants' acts constitute unfair or deceptive acts and practices.

44. Defendants' actions are prohibited by the Consumer Fraud and Deceptive Business Practices Act.

45. The BIESTERFELDS relied on these false statements, causing the BIESTERFELDS to not use other testing as noted above that would have shown the presence of Trisomy 21 in the fetus.

46. But for the false statements of ARIOSA, the BIESTERFELDS would have terminated the pregnancy.

47. Because the BIESTERFELDS were not given the option to terminate the pregnancy, the birth of N.B. has caused them to be responsible for extraordinary expenses until age 18 in the care and treatment of N.B. in excess of $4,000,000, and has caused and will cause future emotional distress.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually and as Representative of N.B., and RONALD BIESTERFELD, pray for entry of judgment against the Defendant ARIOSA DIAGNOSTICS, INC. for the damages incurred by Plaintiffs in excess of $4,000,000, plus punitive damages, together with the costs of this action.

## COUNT II—COMMON LAW FRAUD

48. Plaintiffs refer here, restate and re-allege paragraphs 1-32 as their paragraphs 48-80 of Count II.

81. ARISOA made false statements of material fact in one or more of the following ways:

    a. Fraudulently induced and misrepresented that the ARIOSA Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;

    b. Misrepresenting that the ARIOSA Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;

    c. Misrepresenting the limitations of and alternatives to the ARIOSA Test;

    d. Misrepresenting that the ARIOSA Test is more accurate than traditional first trimester screening tests;

    e. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested;

    f. Misrepresenting the probability and rate at which the ARIOSA Test could produce false negative results; and

    g. Using deceptive advertising to create the image, impression and belief by consumers and physicians that the use of the ARIOSA Test was safe, reliable, and effective for detecting fetal chromosomal abnormalities, and having no reasonable grounds to believe such representations to be true.

82. ARIOSA made the foregoing misrepresentations with the intent that Plaintiffs, and others similarly situated to Plaintiffs, would rely on such misrepresentations.

83. ARIOSA knew or had reason to know that the foregoing misrepresentations were false, unfair or deceptive to Plaintiffs and others similarly situated to Plaintiffs.

84. Defendants made the foregoing misrepresentations or engaged in the foregoing deceptive acts and/or practices in the course of commerce.

85. Due to Defendants' misrepresentations and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and concealing material information, Defendants' acts constitute unfair or deceptive acts and practices.
86. Defendants' actions are prohibited by the Consumer Fraud and Deceptive Business Practices Act.
87. The BIESTERFELDS relied on these false statements, causing the BIESTERFELDS to not use other testing as noted above that would have shown the presence of Trisomy 21 in the fetus.
88. But for the false statements of ARIOSA, the BIESTERFELDS would have terminated the pregnancy.
89. Because the BIESTERFELDS were not given the option to terminate the pregnancy, the birth of N.B. has caused them to be responsible for extraordinary expenses until age 18 in the care and treatment of N.B. in excess of $4,000,000, and has caused and will cause future emotional distress.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually and as Representative of N.B., and RONALD BIESTERFELD, pray for entry of judgment against the Defendant ARIOSA DIAGNOSTICS, INC. for the damages incurred by Plaintiffs in excess of $4,000,000, plus punitive damages, together with the costs of this action.

**COUNT III—NEGLIGENCE**

90. Plaintiffs restate and re-allege paragraphs 1-32 of Count I as their paragraphs 90 through 123 of Count III.

124. ARIOSA sold its ARIOSA Test to the BIESTERFELDS through the DMG OBY-GYN clinic in 2017.

125. It was foreseeable to ARIOSA that parents such as the BIESTERFELDS in considering whether to purchase the ARIOSA Test would rely upon the information ARIOSA provided via: [a] physicians such as those treating KATHLEEN BIESTERFELD at DMG; [b] the ARIOSA brochures; and, [c] ARIOSA's website which set forth 100% reliability.

126. The ARIOSA package information, training, and brochures provided to KATHLEEN BIESTERFELD's physicians were inadequate to advise the physicians of the inherent danger of using this product as a 100% reliable test even though it was not specifically listed in the brochure.

127. The BIESTERFELDS relied on the ARIOSA package information, training, and brochures provided by KATHLEEN BIESTERFELD's physicians.

128. The ARIOSA website omitted and hid information that the test was not 100% reliable to detect Down Syndrome.

129. The BIESTERFELDS viewed and relied on the ARIOSA website.

130. It was foreseeable to ARIOSA that parents such as the BIESTERFELDS would rely on these sources of information and not terminate the pregnancy of a child who in fact had Down Syndrome, thereby causing damages to the parents of the extraordinary expenses until age 18 of providing for the baby and emotional distress.

131. ARIOSA had a duty to warn Plaintiffs that the Ariosa Test was not 100% reliable and would lead to damages to the parents of the extraordinary expenses until age 18 of providing for the baby and emotional distress.

132. ARIOSA failed to warn Plaintiffs, by both omission and hiding information by placement and font size, that the ARIOSA Test was not 100% reliable and could lead to damages to the parents of not terminating a pregnancy of a child with Down Syndrome the extraordinary expenses until age 18 of providing for the baby and emotional distress.

133. ARIOSA's failure to warn Plaintiffs by both omission and hiding information by placement and font size that the ARIOSA Test was not 100% reliable and could lead to a false negative made the test defective.

134. This defect proximately caused damages to the BIESTERFELDS of the extraordinary expenses until age 18 of providing for the baby and emotional distress when they did not terminate the pregnancy in reliance on the warnings given by ARIOSA.

135. The birth of N.B. has caused the BIESTERFELDS to be responsible for extraordinary expenses until age 18 in the care and treatment of N.B. in excess of $4,000,000 and has caused and will cause future emotional distress to the BIESTERFELDS.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually and as Representative of N.B., and RONALD BIESTERFELD, pray for entry of judgment against the Defendant ARIOSA DIAGNOSTICS, INC. for the damages incurred by Plaintiffs in excess of $4,000,000, together with the costs of this action.

Respectfully submitted,

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